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Challenges of Wearable Health Monitors

A Case study of Foetal ECG Monitor

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Abstract—IoT-based wearable health monitoring devices promise multiple benefits such as remote diagnosis, early-warnings, continuous home-care monitoring etc. These technologies will potentially impact people's quality-of-life while reducing costs to healthcare service providers. The challenges for the development of these technologies are manifold, particularly for monitoring bio-signals. In this paper, we discuss the challenges associated with wearable health monitors through a case study of a fetal ECG wearable garment. This is focused on three main areas: a) sensor design and signal conditioning, b) data processing, and communications and c) printed sensors integrated into IoT garments. We discuss in detail the current design challenges to be tackled for achieving a precise signal retrieval.

Keywords—Consumer healthcare, wearable healthcare, ECG sensors, Wearable sensors, Foetal ECG, (key words)

INTRODUCTION

The next revolution in healthcare will be about accurate patient-centric diagnosis, and customized precision healthcare. This will be enabled by Internet-of-Things (IoT)-based medical devices/wearables that can potentially monitor various physiological functions, life style habits and behavioral parameters which was previously possible only in medical centers. It is mainly focussed on how the information that emerges from the interconnected devices is used within the healthcare landscape and can potentially address the current pitfalls within the healthcare sector [1].

“Consumer healthcare” is an industry-coined term which is centered on empowering individuals (consumers) to self-manage their health. It includes all the actions taken by the individual to recognize, treat and manage its own health. They may do this independently or in partnership with the healthcare system, ideally with the aid of technology-enabled monitors and wearables [1]. The core purpose of self-care is to promote and maintain health, prevent disease, cope with illness and disability with the support of a health-care provider. The use of IoT in healthcare extends far beyond the simple adoption of the various monitoring devices.

In the past, weight was the only indicator that was widely monitored on a regular basis. As the use of connected devices has become increasingly popular, the variety of measurements accessible to the public has been constantly on the rise. At present, connected devices generate data used to inform users about health conditions. Dr. Eric Topol draws a list of pathologies [3] where users can learn using about though connected IoT devices:

- Obesity and nutrition disorders: the monitoring of weight, activity level, quantity of ingested and burned calories is monitored using mobile health (mHealth) applications.
- Hypertension: treated better thanks to the dissemination of connected blood pressure monitors, which helps increasing compliance.
- Diabetes: connected glucometers allow monitoring of glycemia and the hemoglobin level in the blood, for adjusting insulin requirements.
- Sleep disorders: new monitoring devices, worn on the wrist or placed on the bed, enable patients to learn more about the phases of their sleep.

In the classic medical system, patients make appointments with doctors if symptoms appear, and follow their advice until the problem disappears. However, chronic diseases such as Asthma or diabetes requires adopting preventive behaviors to not only anticipate complications, but also to act immediately in case these occur. They must learn how to assess their own situation to decide whether to call a doctor. This empowerment of the patient requires a well-supervised therapeutic education based on the use of technology.

The natural extension of consumer healthcare devices is to detect and analyse human electrophysiological signals (bio-signals) employing home-based monitoring systems. These bio-signals can be detected at the surface of the body and are classified according to the functional source of the potential, including, electrocardiogram (ECG, or EKG); electroencephalogram (EEG), electromyogram (EMG) and electrooculography (EOG) [4]. Advances in microcontroller design and wireless communications have made the prospect of constant real time ECG monitoring in a non-clinical setting a viable option. The UK National Health Services (NHS) backed studies show the effectiveness of such a monitoring regime [5].

I. CASE STUDY OF WEARABLE FOETAL ECG MONITOR

During pregnancy, many potential complications such as premature delivery or umbilical cord pressure can arise. At present, any concerns or emergency requests are triggered when such event is identified by the expectant mother. Healthcare providers rely on having the necessary staff and equipment available to identify and attend such concerns promptly. Monitoring fetal ECG (fECG) is an important part of care during pregnancy to ensure the wellbeing of the baby. fECG measurements are currently carried out by trained professionals at the hospital using a either a handheld Doppler ECG monitor or silver chloride electrode-based sensors.

Miniaturization and wearable electronics can be employed to create novel solutions for wireless fECG monitoring, enabling diagnosis and event-based intervention at any given location and time. In the context of long term

monitoring of the health state from a home basis (i.e. during pregnancy), it is necessary for any measurement technique to be non-invasive, reliable, easy to apply by non-specialized personnel, being compact, having wireless IoT capabilities as well as being affordable. Such requirements pose multiple design challenges.

In this paper, we discuss such challenges associated with wearable health monitors through a case study of fECG wearable garment, focused on three main aspects: a) sensor design and signal conditioning, b) data processing, and communication, and c) printed sensors integrated into IoT garments.

SENSING AND MONITORING REQUIREMENTS

The detection of surface physiological signals has shown to be a powerful tool for the diagnosis of clinical conditions. However, the measurement of such signals mainly depend on their amplitude and the spatial resolution at which they are acquired. For a typical surface ECG measurement, the peak deviation of the QRS complex is around 1 - 2 mV on the chest (V1–V5 lead positions) and 0.3 - 0.8 mV on the periphery (I-lead position) [6]. The detection of the fECG during pregnancy becomes more challenging due to its weak amplitude, which is typically of the order of 10 - 100 μ V at the surface of the mother's abdomen [7, 8]. Moreover, the frequency of the fECG signal occupies the same range of frequencies and voltage as many other bio-potentials such as the maternal ECG (mECG) [9], both of which make it difficult to separate the fECG from the maternal ECG.

Home-based wearable health-monitoring devices can be used to detect fetal bio-signals for the early detection of embryonic developmental impairments, and potential complications. There are four main functional areas that pose specific challenges on the provision of reliable patient related information which can be transmitted wirelessly to a remote end user terminal, informing clinicians through the data required for decision making. Figure 1 shows an end-to-end wireless system architecture for the monitoring of fECG signals, including the following functional blocks:

- Electronic sensor design: electrode front-end, analog signal conditioning electronics, analog to digital conversion and signal processing unit.
- Integration with wearable garments
- Wireless interface: Bluetooth, WiFi, RF

Electronic sensor design. Traditional electrodes used to detect ECG signals are based on the use of silver-silver chloride (Ag-AgCl) wet transducing electrodes which convert ionic current on the skin surface to electronic currents for amplification and signal conditioning. [4]. These sensors rely on the use of conducting gel which pose several challenges such as drying out, skin irritation, discomfort and shorting between adjacent electrodes in an array if not carefully placed. These problems make wet electrode systems unsuitable for its use outside the clinical environment and particularly inappropriate for remote clinical wearable ECG monitoring [10]).

Commercially available HR monitors such as Meridian M110, Monica AN24 from Monica Health are based on the use of Ag-AgCl transducing electrodes. At present, these monitors are used in maternity wards requiring skin preparation using gel (electrolyte) to generate a potential difference making electrodes not being reusable. However, motion artefacts due to movement induced potential in surface electrodes can make these technologies inaccurate requiring the electrodes to be repositioned.

The development of alternative techniques such as dry electrodes based on capacitive sensing has been proven to detect ECG activity on premature infants [11]. The main limitations of these sensors are: movement artefacts, triboelectric charge generation due to the friction within the garment and poor subject-sensor coupling. On the other hand, dry electrodes based on Electric Potential Sensing Technology (EPS) [12], have proved to be suitable for monitoring fECG [8] with the potential of being integrated in a wearable garment [13]. This is possible as the EPS sensor does not rely on DC resistive coupling, instead it employs a mode of high impedance capacitive coupling with the surface potential through novel guarding and bootstrapping techniques [4]. These advances allow such sensors to operate across a wide range of bandwidths, being suitable for collecting multiple types of electrophysiological signals.

Examples of EPS sensors include those developed using a metallic titanium (Ti) based central 1 mm diameter electrode coated with a titanium dioxide (TiO_2) coating acting as a dielectric to provide a high dependence between the active insulated electrode and the high input impedance at the sensor front-end. In this EPS version, the encapsulated electrode was used to monitor the heart rate of living zebrafish embryos immersed in saline solution. Results presented in [14], showed that the TiO_2 based electrode provides enhanced biocompatibility properties and reduced noise levels when compared with Ag-AgCl electrodes ($2.5 \mu\text{V} / \text{Hz}^{1/2}$) at the frequencies of interest. This design is suitable for performing measurements in aqueous media, which could be well used for washability purposes if similar technology is employed for developing a garment.

Aiming to reduce triboelectric effects, the adoption of materials such as cotton provide a reduction of electrostatic electricity generation when capacitive sensors are employed for a garment development. However, protection for electrostatic discharge is still required for those scenarios when the device is used in rooms having synthetic floor materials such as nylon, polyester, acrylic etc. Using discrete components for minimizing triboelectric effects should be considered in the sensor front-end.

Fig. 1 shows an overview of a wireless fECG system architecture. Here, electrodes are embedded onto the textiles through screen printing techniques or conductive threads and connected to an analog front-end (AFE), which will provide signal conditioning using analog filtering (0.5–100Hz) [15] and amplification. The main objective is to reduce baseline drift, motion artifacts, power line noise, as well as ensuring a high signal to noise ratio (SNR) though the implementation of guarding techniques, grounding and shielding of components.

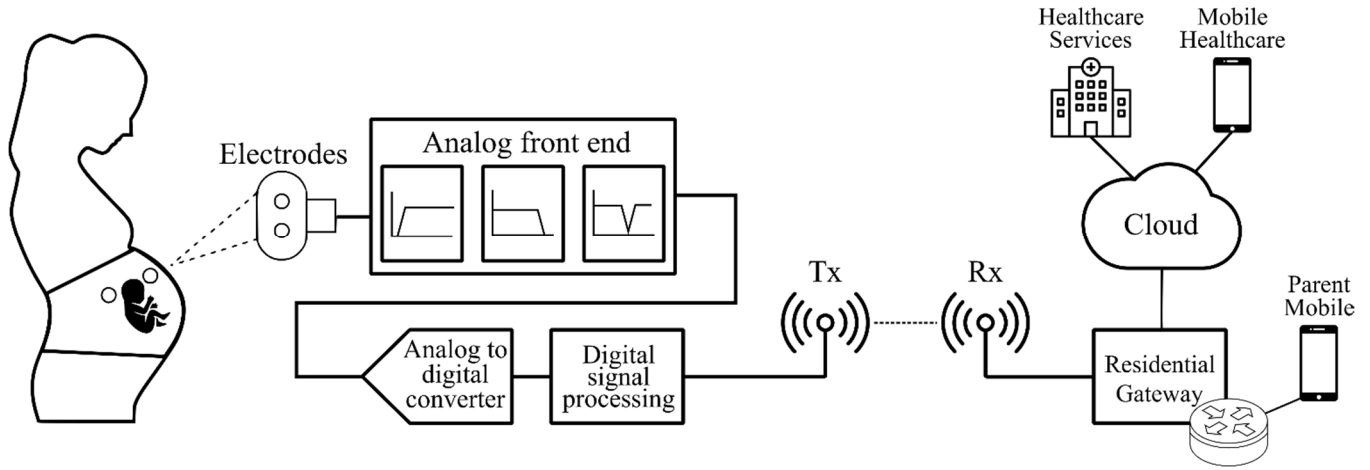


Figure 1: Overview of wireless fECG system architecture

Moving artefacts can be reduced by enhancing the dynamic range of the sensor as well as improving the coupling with the patient. To suppress the mains (line) frequency and its harmonics one solution is to use low-pass analog filtering techniques. To obtain good rejection of 50 Hz, this filter needs a low cut-off frequency and/or high order filter designs. A low cut-off frequency will limit the bandwidth of signals that can be measured, and high order analog filters is costly. Alternative approaches such as using analogue comb filters [4] or digital filters have been employed successfully. An example is a high selectivity digital notch filter, tuned in a smart sensor configuration used to reject unwanted frequencies by up to 95 dB, thereby taking the level below the intrinsic noise floor of the sensor [4, 12]. In both cases, the filters are incorporated into the feedback loop of the sensor, to reduce the front-end sensitivity at the unwanted frequencies and therefore improving its dynamic range.

The relatively low SNR ratio of the fECG can be improved by techniques such as de-noising, adaptive and Kalman filtering or a sensor design that allows for directional acquisition of the signals [8]. The analogue output is then fed into a data acquisition system for analogue to digital conversion, capable of performing the functions of storage processing, and signal packetization for wireless transmission.

As shown in Fig 1, the use system on a chip (SoC) solutions such as those containing an analog to digital converter as well as internal flash memory where digital signal processing (DSP) techniques can be programmed locally will reduce the number of the discrete components required in the AFE. SoC solutions also provide the ability to carry out signal analysis required for data interpretation. Compression of the data and intelligent packet generation will reduce the throughput requirements on the wireless communications stage.

COMMUNICATION REQUIREMENTS

The challenges of the healthcare wireless communication technologies shown in Fig 1 are:

fECG signal characteristics: While there is no general medical consensus on the resolution of fECG recording, the special report from the American Heart Association [15] recommends that analog bandwidth should extend to 150 -250 Hz for infant ECG and sample rates of 500 - 1000 samples per second aiming to capture detailed data from a fECG monitor.

Data Transfer and throughput: Data transfer rate should allow the transfer the parameters of interest such as the fECG in real time without losing fidelity. Low latency is a requirement for real time monitoring together with coverage and reliability for continuous recording.

The data transfer regime can be based on three scenarios:

- I. Constant monitoring: the device is constantly sensing and communicating with a base station to provide real time data for clinical analysis, e.g. heart rate monitoring during surgery.
- II. Scheduled data transfer with on-board storage: fECG data can be stored into an internal memory of the device and downloaded to the base station at regular intervals (daily, weekly, etc.)
- III. Event based data gathering and transmission: the device can perform constant monitoring and will only transmit to a base station when an irregular fECG is detected. An alarm can be triggered, and real time data can be streamed to a hospital/clinician for diagnosis. Real time data will be stored on the device memory for historical analysis as well as on the remote site.

The communication technology should meet the sensor-to-sensor and sensor-to-gateway wide range data rate and throughput requirements. Table 1 summarizes the potential communication technologies that can be used for signal transmission including key aspects such as latency, data rates, coverage ranges and power usage recommended for several communications technologies.

Name	Latency	Data rate (Mb/s)	Range (m)	Power usage
6LoWPAN	< 100 ms	0.25	< 100	Medium
Bluetooth Low Energy (LE)	< 100 ms	0.27	< 50	Low
Bluetooth classic (4.0)	< 1s	2.1	< 100	Medium
WiFi (802.11g)	< 3s	54	< 50	High
ZigBee	< 30 ms	0.25	< 100	Low

Table 1: Typical communication technologies characteristics

Communication Topology and methodology: The choice of topology and connectivity between sensor and gateway could add complexity if traded off for cost and convenience. In addition, the design should include resilience and fail-safe characteristics. Opportunistic networking technologies are being investigated for fail-safe modes [16].

Table 2 summarizes the characteristics of the most commonly used wearable sensor network technologies.

	Battery powered RF WBSN (type 1)	Wirelessly powered WBSN (type 2)	Snap fastener WBSN (type 3)
Comm. method	RF	load modulation	wired
Max. sensors	10-90	48	15
Data rate	50 kbps	10 - 125 kbps	10 mbps
Convenience	very high	high	low
Safety	medium	high	high
Security	low	medium	very high
Operation time	≈ 2 days	≈ 8 days	≈ 14 days
Power source at sensor	flexible or printable battery	no battery (wirelessly powered)	no battery (wire powered)
Potential applications	short term monitoring (ExG, temperature, etc)	long term monitoring (ExG, blood glucose etc.)	monitoring + stimulation

Table 2: Communication Characteristics of wearable body sensor network (WBSN) topologies [16]

The early body wearable sensors also referred to as "body sensor networks" were wired. The integration of wearable sensors was achieved by running "wires" in pockets created in garments for this purpose to connect body-worn sensors. An example of this technology is the MIThril system [17]. However, the wired technology is not conducive for long-term use of health monitoring applications. During the last decade, there has been tremendous progress in the development of numerous communication standards for low-power wireless communication. The key performance metrics for these wireless LOWPAN technologies are: 1) low cost, 2) small size of the transmitters and receivers, and 3) low power consumption. With the development of IEEE 802.15.4/ZigBee [18] and Bluetooth, tethered systems have become obsolete. The recently developed IEEE 802.15.4a standard based on Ultra-wide-band (UWB) impulse radio opens the door for low-power, low-cost but high data rate sensor network applications with the possibility of highly accurate location estimation [19].

Data Transfer and Privacy. Most of the current health IoT devices and apps are in an early stage of development and testing for inter-operability issues between systems should be solved before these can be distributed or commercialized. Improvements in accuracy and consistency are also expected along regulatory requirements. This means that there is still a need for the integration of consumer-generated healthcare data (CGHD) into the mainstream health-care data which is often owned by the government. Regulatory compliance requirements, such as the US Health Insurance Portability and Accountability Act (HIPAA) and EU General Data Privacy Regulation (GDPR), support the protection of privacy at various levels. Healthcare data breaches not only can cause significant adverse personal and social impacts of patients and their families, but also incur a huge cost.

Figure 2 shows the IoT healthcare data security architecture proposed for the case study of a wearable maternal IoT fECG monitor. As shown, personalized data will be shared among nodes, thus data privacy and security will be one of the most important challenges to be solved.

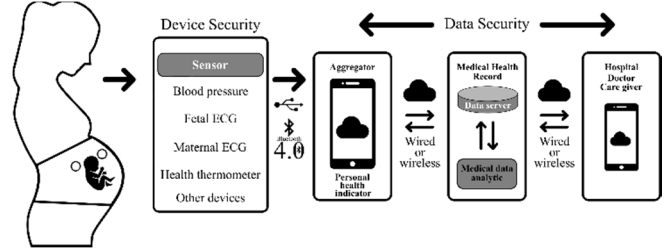


Figure 2: Generic IoT Data security healthcare Architecture

The security challenges relating to healthcare can be broadly classified as data-centric and device-centric. Data-centric concerns are ethical in nature and address data confidentiality, privacy, and data ownership. Device-centric challenges are technical in nature, particularly caused by the devices and wearables because of the need for their availability and constant connectivity for access to services. Disruptions affect the device data streams, and attacks impact the service delivery severely. The impact is not restricted to reputation, financial loss, and customer dissatisfaction but can affect patient safety making this a safety-critical issue. Finally, authentication and identity management of the devices to ensure encryption of data in transit is an existing challenge [2].

SCREEN PRINTED SENSORS REQUIREMENTS

Several design challenges are posed by wearable fECG devices, particularly when integrated into a garment. This include the design of a data processing unit (DPU), wires that connect the sensors and the DPU, and the unit that provides the power for sensing and data communication. The design should meet the following requirements:

- The DPU requires being miniaturized and to be detachable from the garment for washing.
- The wires should be integrated into the garment and be able to sustain bending, stretching and washing up to a given specification.
- The power unit should be replaceable or rechargeable, safe and detachable from garment for washing purposes.

To meet these design requirements the DPU and the power unit can be enclosed into a detachable case for easy removal during washing. A key challenge is to provide sufficient power to the DPU and communication, whilst miniaturizing the battery for the wearable application. Many designs for low-power consumption have been proposed for the electronics. One example is the low-voltage current reuse design that optimizes power in both the current and the voltage domains, achieving up to 1.56μW of power consumption by the amplifier and power management circuitry in a fECG application [20]. Additionally, since the design purpose of this wearable device is for constant monitoring, the power consumption of data transmission will significantly affect the battery-life when large amount of data is produced. It has been found that an on-board signal processing system reduces the

power consumption of wireless transmission [21] because sensing more refined signals requires lower bandwidth. Other techniques such as voltage detection could also provide a solution in reducing the unnecessary data to reduce the power consumption in processing and transmitting data [22].

The wires integrated into the garment can have several design approaches. One common solution is using conductive thread that is sewed into the textiles by weaving. These yarns have high strength, are biologically inert, and the materials are available at relatively low cost. They are also not sensitive to washing or perspiration. The integration of conductive yarns in a structure needs to ensure that the electrically conductive fabric is comfortable to wear and soft to the touch, rather than hard and rigid. The embroidery process increases the cost of integration, and in addition they are heavier than most textile fibers making homogeneous blends difficult to produce. Using this approach, no additional step after the manufacturing of the fabric is required to establish conductivity. Alternatively, printing conductive inks on textiles can be employed.

The conductive inks are usually conductive particles (e.g., Ag, Cu) suspended in a solvent. Either inkjet or screen printing is used to deposit the ink on textiles in a pattern. Inkjet printing can produce thin and fine patterns, but is more time consuming. Screen printing, however, produces thicker layers and is suitable for fast and large-area production. Both techniques require a curing process to solidify the conductive inks after printing. This curing process can be disadvantageous to some textiles if they are sensitive to high temperatures. Unlike the 'conductive thread' approach, conductive inks require an extra water-proof layer to encapsulate the conductive materials for them to be washable.

It has been found that the conductive inks directly printed on textiles crack easily when subjected to bending, thus additional interface layers must be printed on the fabrics before the application of conductive inks. The use of polymer interface layers has been proven to be able to effectively improve the durability of conductive patterns and to withstand bending, stretching, abrasion and washing [23].

CONCLUSIONS

While there is a clear demand and need for wearable healthcare monitors at home and in hospitals, there are still numerous challenges, particularly for monitoring physiological signals such as ECG of the unborn fetus, making the challenge multi-dimensional as discussed in this paper. With respect to monitoring sensors, alternative technologies to the standard AgCl based electrodes such as capacitive sensors need to be considered for its integration within garments. Continuous monitoring of fetal cardiac activity requires considering the signal characteristics as well as those signals that may fall within the same frequency ranges. This will affect the sensor design as well as the analog front end. In addition to this, the acquired data should ideally be processed on board to optimize the amount of data to be sent using a low energy radio (i.e. BLE) and to account for the lower transmission rates.

The design of a garment-integrated fECG sensor should include a detachable case containing units for data processing, data transmission and power. Techniques such as on-board data processing and voltage detection can be used to reduce the power consumption of the electronics, thus allowing further miniaturization of the detachable case. To connect the detachable case to the sensor, wires need to be integrated into

the garment. Potential methods of integration include embroidery of conductive thread and screen printing of conductive inks on textiles.

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